



STATE PROCUREMENT OFFICE
NOTICE OF REQUEST FOR EXEMPTION
FROM HRS CHAPTER 103D

Received by
State Procurement Office
01/22/2016

TO: Chief Procurement Officer
FROM: Health/State Laboratories Division
Name of Requesting Department

Pursuant to HRS § 103D-102(b)(4) and HAR chapter 3-120, the Department requests a procurement exemption for the following:

1. Describe the goods and/or services:

TrepSure EIA for in vitro diagnostic detection of Treponema pallidum (syphilis) antibodies in human serum or EDTA and citrated plasma and various DFA products and Accessories for Culture Confirmation of Viral Agents

2. Vendor/Contractor/Service Provider: BIOPOOL US, INC. dba Trinity Biotech Distribution 3. Amount of Request:
\$ 30,000

4. Term of Contract From: 4/2/2016 To: 4/1/2017 5. Prior SPO-007, Procurement Exemption (PE): 15-043SK

6. Explain in detail, why it is not practicable or not advantageous for the department to procure by competitive means:

It is not practicable or advantageous for the department to procure by competitive means since our laboratory has validated and performs the TrepSure EIA test for syphilis. Our laboratory is required to confirm all reactive sera or CSF for syphilis by HAR 11, Chapter 156. The SLD was able to validate the use of the TrepSure EIA Test with assistance from the Centers for Disease Control and Prevention (CDC) who also performs the TrepSure EIA in-house. Our laboratory previously performed another confirmatory test, FTA-ABs, but due to vendor non-compliance, had to cease performing the assay. During the interim, the CDC was performing all the confirmatory testing for the SLD. It is more advantageous for SLD to have selected this assay, since technical assistance and comparative validation was available and received from the CDC.

It is not practicable or advantageous for the department to procure by competitive means since both manufacturer's products, Biopool US Inc. dba as Trinity Biotech Distribution and EMD Millipore, are currently being used in our laboratory. Previous validation of product performance have been performed on selection of the primary products used for culture confirmation of viral agents.

7. Explain in detail, the process that will be or was utilized in selecting the vendor/contractor/service provider:

The TrepSure EIA was selected for validation since there was excellent correlation of test performance when compared to the Centers for Disease Control and Prevention (CDC) and technical assistance was readily available. Since the SLD and the CDC serve as reference laboratories, it would be advantageous for our laboratories to be running the same assay.

The SLD is currently using both manufacturers/vendors, Biopool US, Inc. dba Trinity Biotech Distribution and EMD Millipore, for DFA products for culture confirmation of viral isolates. The SLD uses the Trinity Biotech products primarily for viral respiratory agents and the EMD Millipore products for culture confirmation for other viral agents including enteroviruses, cytomegaloviruses, Herpes Simplex Virus Types 1 & 2, Varicella Zoster, various control slides, and other accessories including Phosphate Buffered Solution and mounting fluid.

Each reagent has been validated for use in the SLD with both manufacturers serving as back-up for additional products in the event of quality control and supply issues. The TrepSure EIA for syphilis is distributed only by Trinity Biotech and is not available from EMD Millipore. Rabies conjugate is not available from Trinity Biotech.

12997

8. Identify the primary responsible staff person(s) conducting and managing this procurement. (Appropriate delegated procurement authority and completion of mandatory training required).

*Point of contact (Place asterisk after name of person to contact for additional information).

Name

Division/Agency

Phone Number

e-mail address

Gail Kunimoto

State Laboratories/MMB

453-6700

gail.kunimoto@doh.hawaii.gov

All requirements/approvals and internal controls for this expenditure is the responsibility of the department.

I certify that the information provided above is, to the best of my knowledge, true and correct.


Department Head Signature

JAN 21 2016

Date

For Chief Procurement Officer Use Only

Date Notice Posted: 1/22/16

Inquiries about this request shall be directed to the contact named in No. 8. Submit written objection to this notice to issue an exempt contract within seven calendar days or as otherwise allowed from date notice posted to:

state.procurement.office@hawaii.gov

Chief Procurement Officer (CPO) Comments:

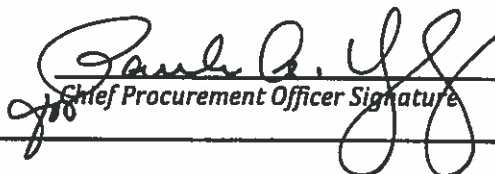
Approval is granted for the period 4/2/2016 to 4/1/2017, based on the department's representation that BIOPOOL US, INC. dba Trinity Biotech Distribution is the only manufacturer of TrepSure EIA test for syphilis and one of the two manufacturers of various DFA products and accessories for culture confirmation for viral agents, and purchasing these validated products from the manufacturer is necessary to receive technical assistance should there be any problem. This approval is for the solicitation process only. HRS section 103D-310(c) and HAR section 3-122-112 shall apply (i.e., vendor is required to show proof of compliance and may use the Hawaii Compliance Express) and the award is required to be posted on the Awards Reporting System. Proof of compliance and the awards posting are required to be documented in the procurement/contract file.

If there are any questions, please contact Carey Ann Sasaki at 586-0575 or careyann.r.sasaki@hawaii.gov.

☒ Approved

☐ Disapproved

☐ No Action Required


Chief Procurement Officer Signature

2-11-2016
Date